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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,706

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Simon L. McGurk

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,706	Applicant(s) MCGURK ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,12 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 9-11,23,29 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,12,14-22,24-28,30-43,47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-5, 7-12, and 14-47 are pending; claims 9-11, 23, 29 and 44-46 are withdrawn; claims 1-5, 8, 12, 14-22, 24-28, 30-43 and 47 are treated on the merits in this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 8, 12, 14-22, 26-28, 30-43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,882,157 to Yang in view of US 6,316,029 to Jain et al.

Yang teaches confectionary delivery systems from anti-cholesterol medicaments. The delivery system includes active drug particles coated with one or more stabilizing materials, such as PEG of instant claim 28. The particles are homogeneously dispersed in gelatin matrices, the matrices comprising gelatin, sweeteners, and other pharmaceutically acceptable materials. The composition has from 1% - 30% water by weight, which substantially overlaps with instantly claimed amount of water. The examples show compositions having the various components within the amounts required by instant claims. The product is formed in rectangular molds, which is a geometric shape. A confectionary is formulated for oral administration. With regard to claim 16, the claim encompasses all types of release profiles, therefore Yang must read

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on it. With regard to claim 18, the alternatively recited types of particles encompass all particles, and is therefore read on by Yang. Yang's preferred drug, cholestyramine, is poorly soluble within the meaning of that term in claims 19-21. Yang's teaching of at least one surface stabilizer is suggestive of two, and the oxyethylene taught as a coating reads on nonionic stabilizers of claim 27. Note that the types of gelatin listed in claim 1 are understood to include any gelatin under the sun, so Yang meets this limitation without specifically specifying the type (natural, synthetic, semi-synthetic) of gelatin.

What is lacking from Yang is the particle size.

Jain discloses a composition having a solid dosage matrix, such as gelatin, a poorly soluble active agent having a particle size of less than 2,000 nm and at least one surface stabilizer on the particles. Note that Jain's composition is quite similar to Yang's, except that Jain's composition is dehydrated, whereas Yang's composition is hydrated.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the particle sizes of Jain in Yang's composition.

Because Yang is silent on the size of the active agent particles, the artisan practicing Yang's invention would look to similar compositions, such as that of Jain, in order to determine the appropriate particle size. Jain provides the particle sizes of instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618